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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kevin Stamp

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EXAMINER

YEH, JENNER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,253	Applicant(s) STAMP, KEVIN	
	Examiner JENNER YEHL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25-32, 39-43, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 33-38 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is responsive to the amendment filed on May 8, 2009. As directed by the amendment: claims 23, 25 and 30 have been amended, claim 24 has been cancelled and no new claims have been added. Thus, claims 23 and 25-46 are presently pending in this application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff et al (US 5865795) in view of Landau (US 6752781).**

Regarding claims 23 and 25, Schiff discloses a needleless injection device with a cylinder 49 (Figure 3) for medicament having an injection nozzle 20 (Figure 3) at a forward end and an opening at its rear end, a piston 50 (Figure 3) sliding in the cylinder, a ram 46 (“plunger”, Col 6, lines 1-2, Figure 3) to drive the piston into the cylinder and having a longitudinal axis, and an energy accumulator 12 (“power unit”, Col 5, line 67, Figure 3) disposed between the ram and a

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discharge assembly, the rear end of the ram extending into the discharge assembly (Figures 3,4). Schiff also discloses the discharge assembly comprising a retention member 68 ("guide", Col 7, lines 5-8, Figure 4) that engages a plurality of retention elements 64 ("ball bearings", Col 7, lines 7-8), where retention elements are spaced around the ram (Figure 4), and a release ring 72 (Figure 4) surrounding the retention elements and preventing radial outward displacement (Col 7, lines 20-21). When release ring is displaced axially, the release ring releases the retention elements and causes discharge of the ram (Col 7, lines 26-32). The retention elements are integral with the retention member and are comprised of heads that move in and out of engagement with a groove on the ram (Figure 18).

Schiff discloses a retention member for engaging a ram but does not disclose the retention member comprising a collet with radially-spreadable fingers. Landau teaches a needleless injection device with a collet 96 (Figure 9) with radially spreadable fingers 98 ("jaw surface", Col 10, line 64; Figure 9) that are biased radially inward (Col 10, line 64) and that "drivingly engages" a ram 226 (Figure 9). The collet moves between one position where the fingers engage with the ram (Figure 10) and a second position where the fingers are spread radially out of engagement with the ram (Figure 9). Thus, it would have been obvious to one of ordinary art in the skill at the time the invention was made to replace Schiff's retention member with Landau's equivalent collet with radially spreadable fingers to achieve the predictable result of engaging the ram.

Regarding claims 26, 27, 30 and 31, Schiff's release ring can be considered a collet lock sleeve, and Schiff modified by Landau as discussed above includes collet fingers as equivalent to Schiff's ball bearings. Since Schiff's release ring limits outward radial movement of the ball

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bearings and is prevented from axial movement by abutment of the ball bearings, then in replacing Schiff's ball bearings with Landau's collet fingers, Schiff's release ring also limits outward radial movement of the collet fingers and is prevented from axial movement by abutment of the collet fingers.

Regarding claims 28 and 29, Schiff's collet lock sleeve 72 ("ring", Col 7, line 20, Figure 4) has a circular inner surface with the arc perpendicular to the longitudinal axis of Schiff's injection device and with horizontal sides parallel to the longitudinal axis of the injection device. Landau's collet 96 and collet fingers 98 (Figure 9) have a circular outer surface with the arc perpendicular to the longitudinal axis of Landau's injection device and with horizontal sides parallel to the longitudinal axis of the injection device. Examiner considers these two surfaces to be "cooperating tapered surfaces".

Regarding claim 32, Schiff discloses the energy accumulator to be compression spring 38 (Col 6, lines 14-19; Col 7, lines 12-15; Figure 4).

3. Claims 39, 40, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff et al (US 5865795) and Landau (US 6752781), and further in view of Weston (US 5891086).

Regarding claim 39, Schiff in view of Landau discloses all the claimed invention but does not disclose a resistance sensitive trigger that is activated by a forward axial force to an axially movable shroud. Weston teaches a needless injection device where the device is triggered by a resistance sensitive trigger comprising an axially moveable shroud 2 ("sliding sleeve", Col

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9, lines 1-11, Figure 5) that forms an outer surface of the injection device and where the trigger is activated by application of forward axial force to the shroud, which is resisted by the skin of the patient at the injection site (Col 9, lines 1-11). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schiff's injection device to include a resistance sensitive trigger comprising an axially moveable shroud forming part of the outside of the device and where the trigger is activated by application of forward axial force to the shroud, as taught by Weston, for the purpose of making the device more convenient and easy to use.

Regarding claim 40, Schiff discloses all the claimed invention but does not disclose a safety lock. Weston teaches a safety-lock ("safety bar", Col 10, line 52) to prevent accidental disengagement of the device (Col 10, line 53) where the lock is moveable between a locked position where the device cannot be discharged and an unlocked position where the device can be discharged (Col 10, lines 52-64). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a safety-lock to Schiff's injection device, as taught by Weston, for the purpose of preventing accidental discharge of the device.

Regarding claim 45, Schiff discloses all the claimed invention but does not disclose a variable volume chamber around the energy accumulator and where the chamber's volume is varied by rotating the ram. Weston teaches a needleless injection device with a variable volume chamber 1 ("tubular body", Col 7, line 19) where the volume of the chamber can be varied by rotating a ram 20 ("tubular member", Col 8, line 43) (Figures 2-4). Varying the volume increases and decreases the compression on the energy accumulator, spring 24, and is a mechanism to adjust the firing force (Col 8, lines 58-62). Thus it would have been obvious to one of ordinary

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skill in the art at the time the invention was made to include a volume variable chamber around Schiff's energy accumulator spring and where the chamber's volume is varied by rotation of the ram, as taught by Weston, for the purpose of controlling dose volume and adjusting the firing force of the injection device.

Regarding claim 46, Weston's ram is turned by a key 6c ("threaded insert", Col 7, line 64) inserted through one end of the device (Col 5, lines 46-48, Figures 2-4).

4. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff et al (US 5865795), Landau (US 6752781) and Weston (US 5891086), and further in view of Slate (US 6669664).

Regarding claim 41, Schiff et al in view of Landau and Weston disclose a needleless injection device with a resistance-sensitive trigger and a safety lock, but do not disclose the safety lock comprising an axially-extending tab that prevents axial movement of the shroud. Slate teaches a needleless injection device with a safety lock comprising an axially-extending tab 68 that serves as an endstop and which in a locked position locks an endcap 40 ("firing cap", Col 7, line 49) and prevents endcap and device from moving axially from each other (Figure 6). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schiff's needleless injector to include a safety lock with a safety locking tab that extends axially and can prevent axial movement of the shroud, as taught by Slate, in order to achieve the predictable result of providing a locking means for Schiff's needleless injection device.

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Regarding claim 42, Slate teaches the tab 68 projecting from a rotatable drive plate 66 ("interlocking ring", Col 7, line 39) that is actuated by a switch 48 (Col 7, lines 38-43). The rotatable drive plate can be rotated to align or misalign the tab in an unlocked or locked position respectively (Col 7, lines 38-50).

Regarding claim 43, Slate's device is in an unlocked position when the tab 68 moves rearwardly into a recess 70 ("slot", Col 7, line 43) on an endcap 40 ("firing cap", Col 7, line 43) (Col 7, lines 38-49, Figure 6).

Allowable Subject Matter

5. Claims 33-38 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

6. Applicant's arguments filed May 8, 2009 have been fully considered but they are not persuasive.

7. Regarding previous objections to the Oath/declaration, drawings and 112 rejections, Examiner respectfully thanks Applicant for clarifying Applicant's position. The previous objections are withdrawn.

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8. Applicant's arguments are 1. Schiff et al's ball bearing and guide are not integral, 2. Landau's collet assembly lacks a "retention member" and a "release ring", 3. Landau's collet assembly is a lost motion preventer and a ratchet mechanism, 4. there is no motivation to combine Landau's collet with Schiff's injection device, and 5. the combination of Schiff in view of Landau does not yield an operable device.

9. In response to applicant's argument that Schiff et al's ball bearing and guide are not integral, Examiner respectfully disagrees. Given the broadest reasonable interpretation of the claim, Schiff's ball bearing and guide are integral in the sense that both components that work together to comprise a whole (ie. guide 68 includes holes which receive ball bearings 64, Col 7, lines 5-8).

10. In response to applicant's arguments that Landau's collet assembly lacks a retention member and a release ring and that there is no motivation to combine Landau's collet with Schiff's injection device, Examiner respectfully disagrees. The Landau reference was used to teach the limitation of a retention member comprising a collet. Schiff et al already disclose a release ring 72 that surrounds retention members, "ball bearings", so that the ball bearings are engaged with the piston when release ring is around the retention members and the ball bearings are released from engagement with the piston when release ring is not around the retention members (Col 7, lines 20-33). Schiff et al disclose a ball-detent gripping mechanism. Landau teaches an alternate gripping mechanism where the retention member is a collet and the collet is of a structure capable of gripping a cylindrical object disposed in the center of the collet (See

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Figure 10) when surrounded by a circular sleeve (See reference number 102 in Figure 10) and capable of radially expanding to release the cylindrical object when the collet is not confined by the circular sleeve (Figure 9). Both Schiff and Landau disclose structure that is confined by a sleeve, capable of engaging with a groove on an object to grip the object, and capable of releasing the object upon release from the sleeve. It has been held that simple substitution of components that serve identical functions is obvious to one of ordinary skill in the art. In the instant case both the collet and the ball bearings and guide serve to engage with a groove on the piston and are capable of being released from this engagement by axial displacement of a confinement sleeve.

11. In response to applicant's argument that Landau's collet assembly is used as a lost motion preventer rather than a gripping mechanism, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Landau's collet assembly is capable of gripping a groove on a piston.

12. In response to applicant's argument that Landau's collet would not be operable in Schiff's injection device because Schiff's ram does not include grooves, Examiner respectfully disagrees. Schiff discloses the ball bearing retention members are disposed within a groove on the ram 46 (See Figure 18 where ball bearings 64 are disposed within a grooved portion of ram 46).

Conclusion

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13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Danielson et al (US 6039303) disclose collet fingers and a ball-detent assembly as equivalents.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNER YEH whose telephone number is (571)270-7836. The examiner can normally be reached on Monday-Thursday, 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. Y./

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763